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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Jonathan Stanley Harold Denyer

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03/06/2009

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EXAMINER

MENDOZA, MICHAEL G

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

03/06/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/781,610	Applicant(s) DENYER ET AL.	
	Examiner MICHAEL G. MENDOZA	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,7,8,12,13,16-20,39-41,44,47,48 and 51-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,7,8,12,13,16-20,39-41,44,47,48 and 51-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. The applicant has noted that claims 7 and 21 are listed as rejected on the cover sheet of the office action, but the office action contains no substantive rejection. The examiner agrees that the claims are not listed in the detailed action. However there is a substantive rejection to the claimed subject matter (claim 3: paragraph 4, lines 2-5, claim 21: all of paragraph 4).
2. Applicant's arguments filed 11/20/2008 have been fully considered but they are not persuasive.
3. As to claim 1, the applicant argues that Gordon does not teach a drug delivery device. The recitation of "for delivery to a patient in a drug delivery device" is a function limitation and is treated as such since the drug delivery device is not positively claimed. Furthermore, the applicant has not given any structural limitations in the claims as to what the drug delivery device comprises. Never-the-less, the device of Gordon holds at least one container. The device is then opened and a container is delivered to a patient.
4. As to claim 3, the applicant argues that the drug is not adapted for delivery in air inhaled by the patient to their lungs. It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only required the ability to so perform, It does not constitute a limitation in any patentable sense, *In re Hutchison*, 69 USPQ 138. Gordon teaches capsules. Capsules are known to hold powders or liquids. Both powders and liquids are capable of being inhaled.

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5. As to claim 12, the applicant argues that Gordon does not teach wherein the memory is configured to store information from the drug delivery device. Gordon teaches reading and storing information from the device onto memory (col. 4, lines 47- col. 5, line 14).

6. As to claim 19, the applicant argues that Gordon does not teach a drug delivery device. The examiner disagrees. The applicant has not given any structural limitations in the claims as to what the drug delivery device comprises. The device of Gordon holds at least one container. The device is then opened and a container is delivered to a patient.

7. As to claim 20, the applicant argues that Gordon does not teach a drug delivery device. The examiner disagrees. The applicant has not given any structural limitations in the claims as to what the drug delivery device comprises besides a chamber for receiving a drug. The device of Gordon teaches chambers into which capsules with drugs are placed.

8. As to claim 13, the applicant argues that Anderson et al. teaches a delivery controller for controlling the amount of the drug delivered to the patient based on receive treatment information. The recitation of "a delivery controller for controlling the amount of the drug delivered to the patient based on receive treatment information" is a function limitation and is treated as such. Anderson et al. teaches a controller that is capable of performing the function. The applicant has not positively claimed that the controller is programmed to perform the limitation. The controller need only be capable of doing so.

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9. As to claims 16-18, Anderson teaches an authorization portion (col. 12, line 11-8), and wherein the drug delivery device is selected from one of a pneumatic nebulizer, a piezo-electric nebulizer, or an ultrasonic nebulizer (Anderson is an air driven/pneumatic nebulizer).

10. Applicant's arguments, see pgs 13-15, filed 11/20/2008, with respect to the rejection(s) of claim(s) 39, 40, and 47 under 35 USC 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Chartrand 5562550.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

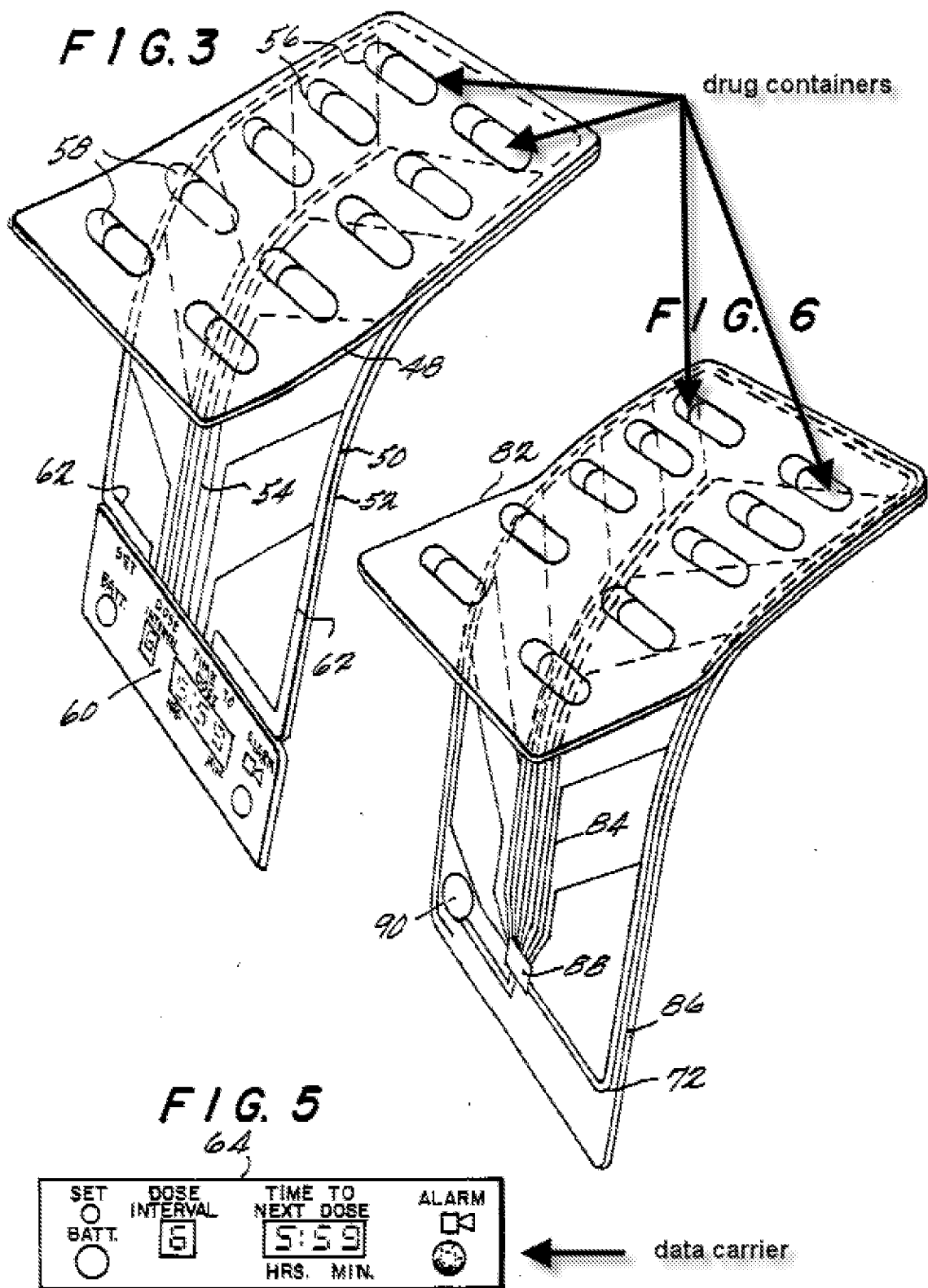
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1, 3, 4, 7, 8, 12, 19-21, 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Gordon 4617557.

13. Gordon teaches a drug package comprising: a least one container containing a drug; an electronic data carrier including a memory, the electronic data carrier further includes a radio frequency device; wherein the electronic data carrier is arranged to supply the drug treatment information a number of times corresponding to the number of treatments available from the drug package, or the number of containers included in the drug package (col. 2, lines 22-30); wherein the at least one container is a plurality of

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containers and wherein the electronic data carrier is a single electronic data carrier;
wherein the memory stores information; wherein the drug treatment information includes
at least one of the following items: an identity of the drug which is to be delivered; a
security code; a desired amount; a desired frequency of treatment; or an expiration date
(col. 2, lines 22-30).



Claim Rejections - 35 USC § 103

14. Claims 39-41, 44, 47, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon in view of Chartrand 5562550.

15. As to claim 39, 40, and 47, Gordon teaches a plurality of drug containers, each container containing a drug; and an electronic data carrier separate from the drug containers, the carrier including drug treatment information. It should be noted that Gordon fails to teach wherein the data carrier is arranged to be powered inductively from a radio frequency signal. Gordon teaches that the data carrier is powered via a battery.

16. Chartrand teaches a device with a data carrier arranged to be powered inductively from a radio frequency signal as opposed to the battery powered data carrier taught by Gordon. Therefore, it would have been obvious to use a data carrier arranged to be powered inductively from a radio frequency signal an alternative to battery powered data carrier, because they are expedients of each other. Furthermore, inductively powered data carriers are well known in the art of electronics.

17. Claims 1, 13, 19, and 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. 5237987 in view of Gordon.

18. As to claims 13 and 19, Anderson et al. teaches a drug delivery device; a delivery portion (52); an electronic input (228) arranged remotely from the delivery portion; and electronic data carrier removable from the drug delivery device (see claim 5); a delivery controller (28); a memory located within the electronic data carrier; and an

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output. It should be noted that Anderson et al. fails to teach transmitting treatment information via a radio frequency signal.

19. Gordon teaches a device with an output for transmitting treatment information via a radio frequency signal as opposed to the circuitry taught by Anderson et al. for transmitting information. Therefore, it would have been obvious to use a radio frequency signal as an alternative to circuitry for transmitting information because they are expedients of each other. Furthermore, wireless connectivity is well known in the art of electronics.

20. As to claims 16-18, 51, and 52, Anderson/Gordon teaches the device according to claim 13, wherein the drug delivery device includes an authorization portion (col. 12, lines 11-18); wherein the drug delivery device is selected from one of a pneumatic nebulizer, a piezo-electric nebulizer, or an ultrasonic nebulizer (Anderson is an air driven/pneumatic nebulizer).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL G. MENDOZA whose telephone number is (571)272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. G. M./
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734